

## **REMARKS**

### **I. Amendments**

Claim 5 has been amended to incorporate the embodiment of claim 6, now canceled, and to enter a number of formal amendments. Claim 7 has been amended to remove a dependency on cancelled claim 6.

The specification has been amended to provide a brief description of Figure 1. Support is provided by the drawing sheet itself and the specification at page 8, lines 10-21.

The Examiner alleges that the application does not contain an Abstract of the disclosure as required by 37 C.F.R. §1.72(b). Applicants reply that an Abstract was provided in the underlying PCT application, PCT/SE2004/001819, which was published as WO 2005/058321 with the Abstract on its title page. A copy of WO 2005/058321 was submitted with the original application transmittal papers. Nevertheless, Applicants are providing the Abstract on a separate sheet as part of this paper. The Abstract submitted herewith is identical to the Abstract found on the title page of WO 2005/058321.

No new matter has been added by any amendment herein.

### **II. Information Disclosure Statement**

The Examiner returned an initialed copy of Applicants' Form PTO/SB/08A, submitted as part of the Information Disclosure Statement ("IDS") filed on June 8, 2006, with the Office Action mailed on May 25, 2007. However, one of the documents listed on the Form, WO 2004/058754, was crossed out, indicating the Examiner did not consider the document.

Applicants' Agent contacted the Examiner for clarification, and was informed that a copy of WO 2004/058754 was not provided as part of the IDS. However, Applicants' submission did include a copy of this document, as confirmed by the PTO's date stamp on Applicants' return receipt included with the application. A copy of the return receipt is submitted herewith.

The Examiner said that she would consider the document if resubmitted with Applicant's response to the outstanding Office Action. Accordingly, Applicants are concurrently filing a Supplemental IDS providing a duplicate copy of WO 2004/058754, and request that the Examiner initial the Form PTO/SB/08A attached to the IDS confirming that this document was considered.

### **III. Provisional Obviousness-Type Double-Patenting**

Applicants note that claims 5, 7, and 8 are provisionally rejected on the ground of non-statutory obviousness-type double-patenting as allegedly being unpatentable over claims 8-14 of co-pending application Serial No. 10/582,388.

Since the rejection is provisional, Applicants will respond to the rejection at such time that the claims of either application have been patented.

### **IV. Claim rejections - 35 U.S.C. §112, first paragraph**

Claims 5-8 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleges that there is insufficient written description for the treatment of a functional gastrointestinal disorder comprising administering a metabotropic glutamate receptor 5 (mGluR5) antagonist.

Claim 5 has been amended to recite the indication of claim 6, now canceled. Accordingly, amended claim 5 is directed to a method of treating functional dyspepsia by administering a mGluR5 antagonist. On page 4 of the Office Action, the Examiner has acknowledged that the specification describes methods of treating functional dyspepsia.

Furthermore, Applicants submit that it is not fatal to the written description requirement that 2-methyl-6-(phenylethynyl)-pyridine (MPEP) is the only disclosed mGluR5 agonist. Section 2163(I)(A) of the M.P.E.P. suggests that the claimed invention as a whole may be adequately described when there is a *“described or art-recognized correlation or relationship between the structure of the invention and its function”*. Similarly, Section 2163(II)(A)(3)(a)(ii) of the M.P.E.P. provides the following:

- ii) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied...by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus...(Citation omitted)

Applicants submit that such a correlation between function and structure is described in the specification. For example, it is disclosed in the specification at page 1 that metabotropic glutamate receptors (mGluR) are G-protein coupled receptors which are involved in the regulation and activity of many synapses in the central nervous system. Page 1 of the specification discloses four documents regarding various aspects of mGluR activity. At least with respect to mGluR5, it is known that this subtype of mGluR is characterized by a structural similarity, i.e., a sequence similarity, and a functional similarity, i.e., activates phospholipase C and increases neuronal activity (See, p. 1, lines 20-30).

Furthermore, on pages 5-8 of the specification, the working example demonstrates a nexus between mGluR5, mGluR5 antagonists and the treatment of functional dyspepsia using this class of compounds. If a compound is a mGluR5 antagonist, then there is a strong presumption that it will be useful in the treatment of functional dyspepsia.

Applicants submit, therefore, that the disclosure of the species MPEP is sufficient to provide written support for the genus mGluR5 antagonist in view of the common structural and functional characteristics of the subtype mGluR5. Although the experimental section presents data for a single compound (MPEP), the specification conveys with reasonable clarity to those skilled in the art, that as of the filing date, Applicants were in possession of the invention as defined by amended claim 5.

For all of the foregoing reasons, the skilled artisan having knowledge of the common structure and function of the subtype mGluR5 would recognize that Applicants had possession of the claimed invention, i.e., treating functional dyspepsia by administering an mGluR5 antagonist. Withdrawal of the rejection under § 112, first paragraph, for lack of written description is requested.

## **V. Conclusion**

Upon entry of this Amendment, claims 5, 7, and 8 remain pending. Applicants respectfully submit that claims 5, 7, and 8 are in condition for allowance. No new matter has been added by any amendment herein.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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